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TECHNICAL PERSPECTIVE
A Balloon-Tipped Catheter for Measuring Urethral Pressures

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Abstract

Background: Better methods are needed for recording urethral function for complex urologic problems involving the bladder, urethra, and pelvic floor.

Objective: To evaluate a balloon catheter for recording urethral pressure and function using bench-top testing and evaluation in an animal model.

Methods: Balloon pressure–recording methods included slightly inflating the balloon with water and placing the pressure transducer on the distal end of the catheter. For bench-top testing, manual procedures and a silastic tube with a restriction were used. In 3 anesthetized dogs, pressure recorded from the skeletal urethral sphincter was induced with electrical stimulation of the sphincter. Anal sphincter pressure was also recorded.

Results: Bench-top testing showed good pressure recordings, including a confined peak at the tube restriction. Animal tests showed urethral pressure records with rapid responses when electrical stimulation was applied. Peak pressure at the urethral skeletal sphincter was 55.7 ± 15 cmH_2O, which was significantly higher than the peak pressure recorded 2 cm distally in the proximal urethra (3.3 ± 2.3 cmH_2O). Peak anal pressures were smaller and unchanged for the 2 stimulations.

Conclusions: Balloon-pressure recordings showed rapid responses that were adequate for the tests conducted. In the animal model, high-pressure contractions specific to the skeletal urethral sphincter were shown. Balloon-tipped catheters warrant further investigation and may have applications for the evaluation of detrusor-sphincter dyssynergia after spinal cord injury or for stress urinary incontinence.

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INTRODUCTION

Better methods are needed for recording urethral function for complex urologic problems involving the bladder, urethra, and pelvic floor. For example, better urethral pressure recording might assist with the evaluation of stress urinary incontinence and detrusor-sphincter dyssynergia (DSD) after spinal cord injuries. Currently, a variety of urodynamic measures, including bladder and abdominal pressures, urine flow rates, and pelvic floor or urethral sphincter electromyography, are used in these evaluations. For direct urethral pressure recording, pressure-tip transducer catheters are often used. However, these catheters only record pressure within the urethra in one direction, they are expensive, and they are not disposable.

As an alternative, balloon-tipped catheters in the urethra have been investigated (1,2). Typically, a side hole in the catheter connects to the balloon, and the catheter, filled with water, is connected to an external pressure transducer. Problems have been reported with this technology, including (a) spread of the pressure along the balloon length, (b) averaging of urethral pressures from different points, (c) difficulty keeping the system free of air bubbles, and (d) the need for frequent calibrations (1,2).

Recently, these concerns have been addressed with a commercial balloon-tipped pressure-recording system (T-DOC, Wilmington, DE). Features of the catheter

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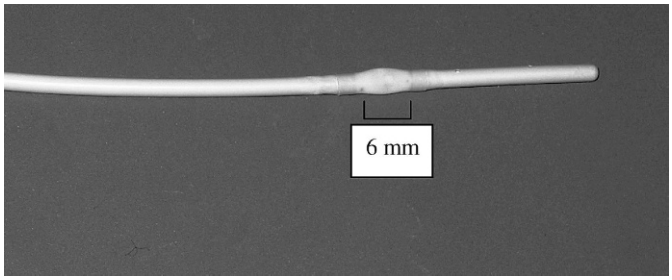

Figure 1. *Three-channel, urodynamic catheter showing the balloon ready for pressure recording after setup procedures that included filling the balloon with water to 0.04 mL.*

include slightly filling the balloon with air and the use of a pressure transducer on the distal end (3,4). In this study, we evaluated a balloon-tipped-catheter (3-channel urodynamic catheter, Cook Urological Inc, Indianapolis, IN) using water rather than air as a pressure-recording medium. Both bench-top and animal testing were conducted. In the animal model, pressure-recording responses of the balloon were assessed during electrical stimulation of the skeletal urethral sphincter.

METHODS

A urodynamic catheter with a small balloon was tested (Figure 1). The catheter diameter is 7.4 F (2.4 mm) and has 3 channels. One channel goes to the balloon, the second is an open tube for bladder filling, and the third is an open tube for recording bladder pressure. The balloon is 6-mm long and is located 4 cm from the tip of the catheter. The balloon is normally inserted into the bladder during catheterization and expanded with 2 ml of air to prevent the catheter from coming out of the bladder. The distal end of the tube from the balloon has a fill-and-release valve. This valve is open when a luer-lock connector is placed in it but is closed when the connector is removed. This allows for the balloon to stay expanded in the bladder after it is filled. In this study, the balloon was used for pressure recording. A 3-way connector with a luer-lock fitting was placed on the fill-and-release valve so that the valve was always open, and this allowed for continuous pressure recording.

Four steps were followed for setting up the balloon for pressure recordings. First, air was removed from the balloon. A 3-way connector was placed on the fill-and-release-valve end of the tube that is connected to the balloon. For the suction procedure, a 60-mL syringe containing 5 mL of water was connected to the connector. The syringe was held vertically and then the plunger was pulled the full length of the syringe, creating a strong vacuum in the catheter balloon and tubing. When the syringe was slowly released, part of the 5 mL of water went into the tubing and balloon. The balloon was checked for bubbles by expanding the balloon with 1 mL of water. The suction procedure was repeated if bubbles were present. The 60-mL syringe was then removed, with care taken to keep the 3-way connector vertical so that it remained full of water.

Second, the balloon was stretched to reduce the internal balloon pressure. The pressure within the balloon can exceed 200 cmH_2O and, in conjunction with urethral pressures, may exceed the maximal recording pressure of some urodynamic equipment. For urodynamic equipment in which this might be a problem, stretching of the balloon is needed to reduce the balloon's internal pressure. The balloon was filled with and emptied of 1 mL of water 4 times, and this reduced the balloon internal pressure by approximately 40 cmH_2O.

Third, a pressure transducer (WPI Inc, Sarasota, FL) was connected to one of the ports of the 3-way connector on the fill-and-release valve. The air was flushed out of the transducer, and a luer-lock stopper was placed on the open end for pressure recording.

Fourth, a 1-mL syringe was placed on the third port of the 3-way connector. During attachment, 0.2 to 0.3 mL of air was expressed from the syringe to ensure that there were no air bubbles in the connector. Then, 0.04 mL of water was added to the balloon, which caused a slight expansion (Figure 1). The pressure within the balloon was then set to zero. Setting this internal balloon pressure to zero did not interfere with recording pressure changes from outside of the balloon.

Occasionally, a slowly declining pressure was seen after filling the balloon with 0.04 mL of water. We checked for leaks and pushed the luer-lock connections tighter or replaced the 3-way connector to stop the decline.

After the setup procedures were performed, bench-top testing was conducted. In one test, the balloon was pulled through a silastic tube (6.6-mm inner diameter, 9.5-mm outer diameter; silicone rubber tubing, Sil-Med Corp, Taunton, MA) with a restriction. The restriction was made by tying wire around the tube; the inside diameter at the restriction was 4 mm (13F). This allowed the 7.5F urodynamic catheter to pass unobstructed. Because the balloon had a slightly larger diameter than the catheter, the restriction was engaged. For the test, the balloon was pulled through the restriction at a rate of 1 mm/s. In 2 other tests, we evaluated the fidelity of the pressure recording. In the first, we raised and lowered the balloon 10 cm with our hands. In the second, we repeatedly squeezed the balloon with our fingers. The pressure from the transducer was amplified (Gould Inc, Cleveland, OH) and recorded on a 9-channel strip-chart recorder (Astro-Med Inc, West Warwick, RI).

Additional studies were conducted in 3 anesthetized female dogs as part of a pelvic nerve stimulation protocol. These studies received Institutional Animal Care and Use Committee and institutional approvals. Two probe electrodes were made from a nerve block needle (HN1, Professional Instruments, Houston, TX). The last

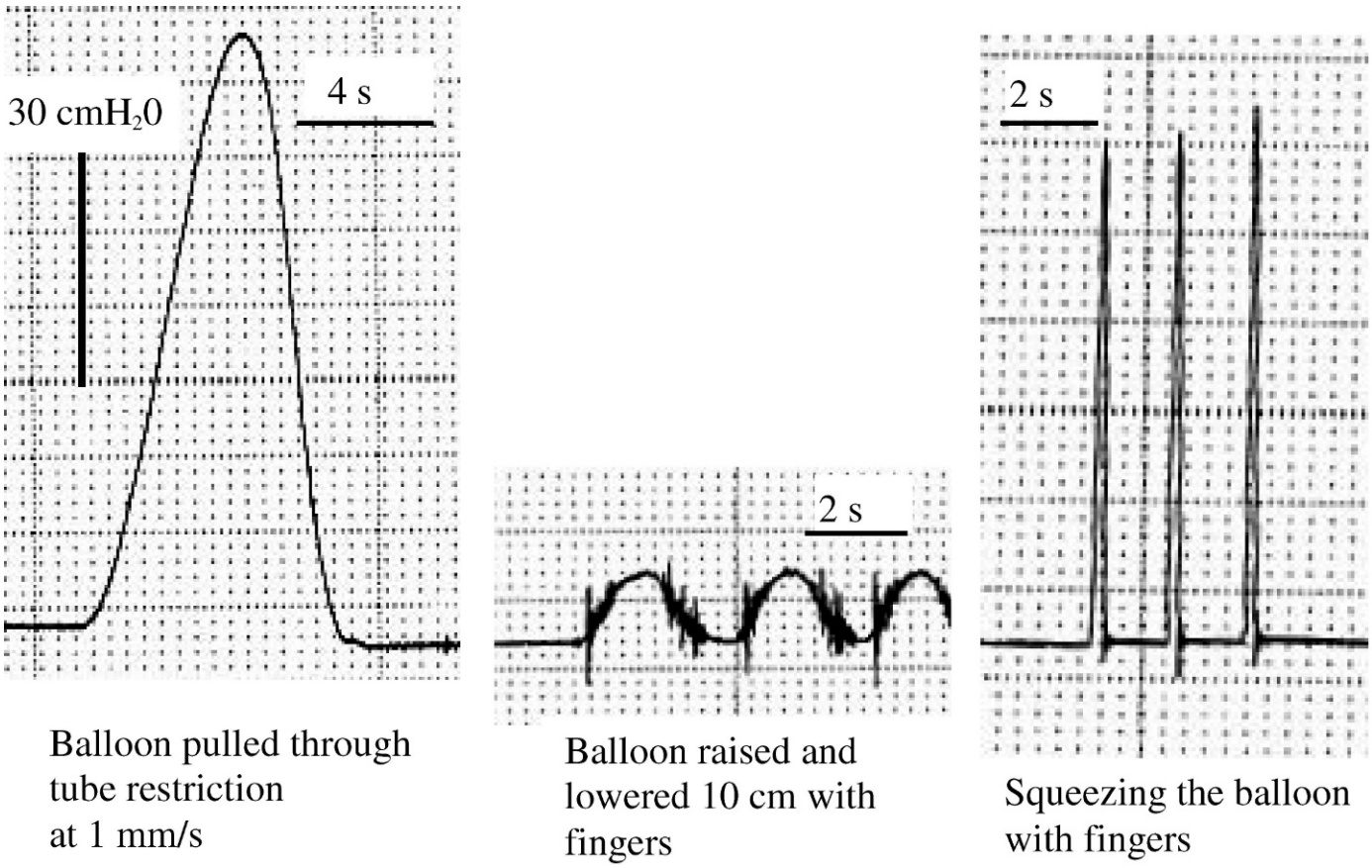

Figure 2. *Bench-top testing of balloon pressure after setting up for pressure recording. LEFT, balloon pulled through a tube restriction showing a confined peak; MIDDLE, balloon raised and lowered 10 cm by investigators showing good fidelity; RIGHT, good fidelity shown from responses to short squeezes of the balloon by the investigators using their fingers.*

8 mm of the needle was stripped of insulation and bent 30° to form the stimulating electrode. General anesthesia was induced with sodium thiopental anesthetic (2 mg/kg, intravenous) and maintained with respiratory anesthetic (2%–3% isoflurane). Animals were placed in a supine position, prepped, and draped in the usual sterile manner. An 8-in midline incision was made from the caudal end of the pubic bone to the midabdominal area, and hemostasis was maintained with electrocautery. Methods described above for the balloon setup were used, and the balloon was inserted into the urethra from the meatal opening and advanced to the caudal end of the pubic bone, where the external skeletal sphincter is located. The 2 probe electrodes were held by the investigators external to the urethra and next to the sphincter. Bilateral stimulation was performed with the electrodes approximately 1 cm apart. Stimulators (Model S48, Astro-Med) with constant current and stimulus isolation were used at 40 pulses per second with a 200-μs pulse duration for 2 seconds and at a current to obtain a strong skeletal urethral contraction (10–15 mA).

Anal pressures were also recorded along with urethral pressures. A rectal balloon (Cook Urological Inc, Indianapolis, IN) was modified for this recording by placing silastic on both ends of the balloon. The resulting dumb-bell shape of the balloon maintained the balloon in the anal sphincter for pressure recording.

RESULTS

Figure 1 shows the balloon ready for pressure recording after the 5-step setup procedures described in the Methods section. Figure 2 shows results from bench-top testing. On the left of this figure, the balloon is being pulled through the tubing with a restriction. The record shows a confined peak. The middle record shows pressure changes during raising and lowering the balloon 10 cm. The records show good reproducibility and frequency response. High-frequency fidelity was indicated in records that showed small pressure changes, which indicated vibration. On the right, a rapid pressure response to short squeezes of the balloon is shown. These records also show rapid onset followed by a decline to baseline.

Figure 3 shows testing in the animal model. On the left, the pressure-recording balloon is located at the external urethral sphincter. Stimulation induced a rapid, strong contraction of the sphincter that was sustained for the 2 seconds of stimulation at 62 cmH_2O. A rapid decline in pressure is shown after the end of stimulation. At the same time, the anal sphincter balloon recorded a peak pressure of 8 cmH_2O. On the right side of Figure 3,

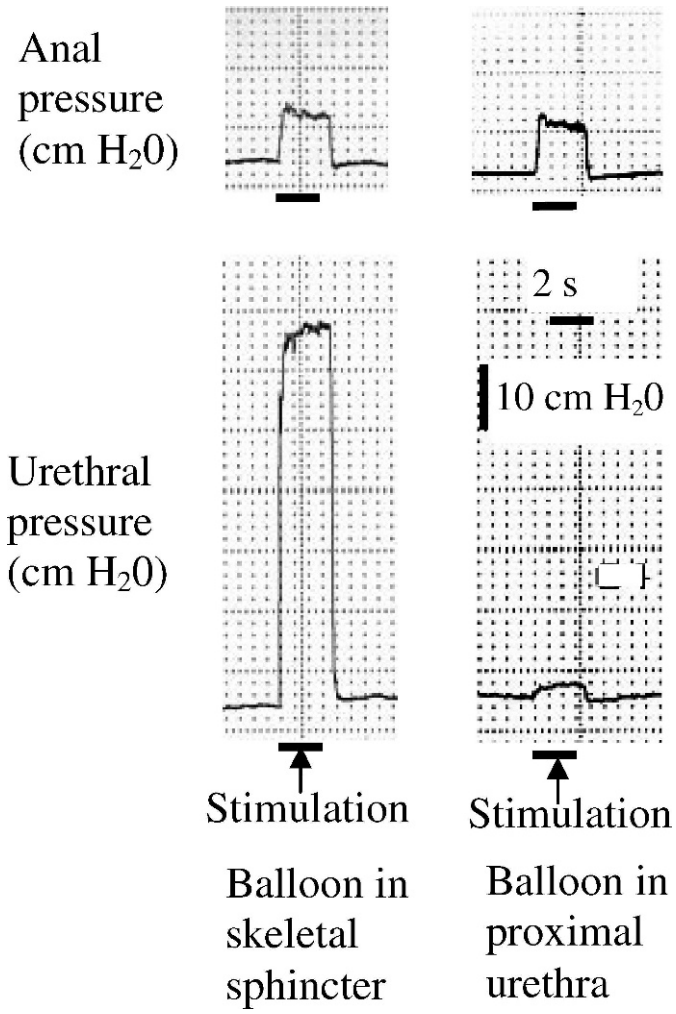

Figure 3. *Urethral and anal pressure recordings during urethral stimulation in the anesthetized dog and after setup of the balloon for pressure recording. Both stimulations with probe electrodes adjacent to the skeletal urethral sphincter. LEFT, pressure-recording balloon located at the external urethral sphincter; RIGHT, pressure-recording balloon located in the proximal urethra, 2 cm proximal to the external sphincter. Stimulation was at 10–15 mA, 40 pulses per second, applied for 2 seconds.*

the urethral balloon was moved 2 cm toward the bladder. Stimulation of the skeletal sphincter resulted in only a 2-cmH_2O increase in urethral pressure. As expected, the anal sphincter pressure was unchanged. The records show that the balloon catheter can be used to record rapid changes in pressures of the sphincter. In addition, direct stimulation of the sphincter shows remarkable contraction strength.

Two additional animals were stimulated at 10 mA, which also induced strong skeletal urethral contraction. Average peak pressures at the sphincter for the 3 animals were 55.7 ± 15 cmH_2O, which were significantly higher than recorded 2 cm proximal in the urethra (3.3 ± 2.3 cmH_2O). Peak anal pressures were not significantly different for both stimulations at 18.7 ± 18.5 and 22.7 ± 25.4 cmH_2O.

DISCUSSION

The water-filled balloon showed good fidelity for pressure recording. Testing in the tube showed confined peak pressures, and additional bench-top testing showed good responses to movement or squeezing (Figure 2). The records in the urethra showed location selectivity with rapid responses and pressures returning to baseline (Figure 3).

Features of this balloon that may address prior concerns with pressure recording are the short length of the balloon and its small rounded surface (Figure 1) (1,2). The steps for the balloon setup are more extensive than for a commercial balloon pressure–recording catheter (T-DOC) that uses an air-filled balloon (3,4). However, the T-DOC only works when using a T-DOC pressure transducer, which might result in an electronic problem associated with switching to a different transducer. In contrast, with the balloon catheter evaluated here, any pressure transducer can be used. In addition, uncompressible water can be expected to provide better pressure recording fidelity than air.

The strong skeletal urethral contractions to electrical stimulation suggest that this method should be investigated for treatment of stress urinary incontinence (5–9). We are currently conducting clinical investigations for this indication. In addition, the balloon-tipped catheter could be evaluated for use in the evaluation of patients with stress incontinence. The 3-channel catheter used here would also allow bladder pressure to be recorded.

We are particularly interested in the potential for this balloon-tipped catheter in evaluation of DSD after spinal cord injury. Historically, 3 classification systems have been used (10,11). In the first, Yalla et al (12) graded DSD based on poor voiding responses during bladder contractions. In the second system, Blaivas et al (13) characterized DSD based on the anal sphincter electromyography. They used 3 categories: (a) ''a crescendo increase in electromyographic activity that reached a maximum at the peak of detrusor contraction,'' (b) ''clonic sphincter contraction that coincided with detrusor contraction,'' (c) ''a sustained sphincter contraction that coincided with detrusor contraction.'' In the most recent classification system, Weld et al (12) is a great advancement. Weld et al (12) based their evaluation on the consistency of the sphincter contraction during the detrusor contraction; 269 patients with suprasacral lesions were classified. Seven percent had no external urethral sphincter obstruction; 80% had intermittent, and 13% had continuous obstruction. The continuous or worse DSD correlated with complete upper–motor-neuron injuries. However, issues related to classifying and understanding DSD still remain. For example, is urethral closure sustained throughout long bladder contractions? In addition, the relative roles of the smooth

muscle of the proximal urethra and the skeletal urethral sphincter in these adverse urethral responses are not clear (15). Proposed balloon pressure–recording methods could be used to help answer these questions. However, there are limitations to the use of balloon technology. The balloon catheter could provoke sphincter contractions, giving artificial readings. Also, these types of measurements could provoke autonomic dysreflexia.

Another area of limitation with this technology is that sphincter recording is not currently the standard for assessing DSD. For this assessment, the most important urodynamic evaluation is the interaction of the bladder and sphincter function in which pressure flow studies are essential. Nosseir et al (16) recently summarized this urodynamic assessment of DSD: ''The cut-off value for storage pressure that safely prevents renal damage is not easy to define. McGuire demonstrated that patients with a detrusor leak point pressure <40 cmH_2O had a lower risk of sustaining upper tract damage compared with patients with a detrusor pressure >40 cmH_2O. Other authors concluded that bladder-filling pressure (which is not necessarily the same as detrusor leak point pressure) <40 cmH_2O is sufficient to preserve the upper urinary tract. McGuire regards a storage pressure of <30 cmH_2O as crucial for the protection of renal function. Besides elevated storage pressure, urinary tract infection and its associated complications are the most significant causes of renal deterioration.''

Thus, frequent urodynamic assessments are important. The most common management of DSD uses intermittent catheterization to drain the bladder; thus, by passing the sphincter. For individuals using reflex voiding for bladder management, alpha blockers, sphincterotomy, or botulinum toxin injections into the sphincter usually need to be part of DSD management (15). In the future, balloon-tipped catheters should be compared with other standard urodynamic methods for assessment of DSD to help determine the best method of bladder management.

CONCLUSIONS

Balloon-pressure recordings showed rapid responses during bench-top testing and in an animal model. In the animal model, high-pressure contractions of the skeletal urethral sphincter in response to electrical stimulation were shown. Balloon-tipped catheters warrant further investigation and may have applications for the evaluation of DSD after spinal cord injury or for stress urinary incontinence.

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